

REMARKS

The Applicant appreciates the courtesy and time of Examiners Ariani and Lankford provided in the telephonic interview of September 3, 2008. The Applicant's representative confirms that the pending claims and the prior art of record were discussed, and that agreement was reached on the patentability of Claim 24, as described in the Interview Summary dated September 10, 2008.

Claims 23, 24, 26, 27, 29, 31, 33, 35, 38, 40, and 48-50 are presently amended as indicated. Entry of the amendments is respectfully requested. Support for the amendments can be found in the specification and claims as filed. Support for the amendments to Claim 23 can be found at least in FIG. 1, page 38, line 8 to page 40, line 6, and page 53, lines 4-6 of PCT/ZA2003/000093 (corresponding to paragraphs [0118], [0119], and [0140] of the specification as published as US 2006/0257372 A1). As noted below, documents are submitted herewith clearly stating that *Megasphaera elsdenii* strain CH4 was deposited under the provisions of the Budapest Treaty and was given the accession number NCIMB 41125 by the International Depository Authority, NCIMB Ltd. Support for "at least a 97% similarity to a 16S ribosomal RNA sequence of the *M. elsdenii* strain deposited at NCIMB, Aberdeen, Scotland, UK under number NCIMB 41125" can be found at page 53, lines 4-6 of PCT/ZA2003/000093. Support for "a growth rate on lactate medium of at least about 0.10 h⁻¹ at pH 4.5 and about 0.86 h⁻¹ to about 0.94 h⁻¹ at pH 5.5" can be found at page 38, line 8 to page 40, line 6 of PCT/ZA2003/000093. No new matter is added.

Submitted herewith are true copies of the "NOTIFICATION OF ACCEPTANCE OF A DEPOSIT FOR THE PURPOSES OF PATENT PROCEDURE" ("the Notification of Acceptance") dated 19 March 2002, signed by Terence Dando, B.Sc., M.Phil., of NCIMB Ltd., and the accompanying forms BP/4 "RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT" ("the Receipt") and BP/9 "VIABILITY STATEMENT," both also dated 19 March 2002, labeled "EXHIBIT A". Both the Notification of Acceptance and the Receipt clearly state that *Megasphaera elsdenii* strain CH4 was deposited under the provisions of the Budapest Treaty and was given the accession number NCIMB 41125 by the International Depository Authority,

NCIMB Ltd. In In re Lundak, the Court of Appeals of the Federal Circuit concluded that “the insertion of depository data after filing is not new matter under 35 U.S.C. §132.” In re Lundak, 773 F2d 1216, 227 USPQ 90, 96 (Fed. Cir. 1985).

Declaration under 37 C.F.R. § 1.132

The August 1, 2008, Office Action stated on page 2 that the Declaration under 37 CFR 1.132 filed on April 29, 2008, was insufficient to overcome the rejection of claims 23, 24, and 26-57 based upon Leedle et al. as set forth in the last Office action on the grounds that an affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness. As noted above, the depository data presented herewith demonstrate that the terms “strain CH4” and “biologically pure bacterial culture of the *M. elsdenii* strain deposited at NCIMB, Aberdeen, Scotland, UK under number NCIMB 41125” refer to the same strain of *M. elsdenii*. Thus, the Declaration under 37 CFR 1.132 filed on April 29, 2008, does compare the claimed subject matter to the cited prior art.

Objections and Rejections Withdrawn

The Applicant gratefully acknowledges that the objection to claim 55 has been withdrawn due to the Applicant's amendments to the claims filed on 29 April 2008.

The Applicant further acknowledges that the rejection of claims 51-57 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention has been withdrawn due to the Applicant's amendments to the claims filed on April 29, 2008.

Claims 23, 24, and 26-57 were rejected previously under 35 U.S.C. §103(a) as being unpatentable over Leedle et al., U.S. Patent No. 5,380,525. While the August 1, 2008, Office Action stated that Declaration under 37 CFR 1.132 filed on April 29, 2008, was insufficient to overcome the rejection of claims 23, 24, and 26-57 over the Leedle et al. reference, that rejection was not maintained and new grounds of rejection were raised. Thus, the rejection of claims 23, 24, and 26-57 under 35 U.S.C. §103(a) as being unpatentable over Leedle et al., U.S. Patent No. 5,380,525 is deemed to be withdrawn.

New Claim Rejections

Rejections under 35 U.S.C. §112, first paragraph

Claims 23 and 26-57 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 26, 27, 29, 31, 33, 35, 38, 40, and 48-50 as amended are dependent on Claim 24. Claims 26-57 are thus directly or indirectly dependent on Claim 24.

Claim 23 as currently amended includes three major limitations:

1. a biologically pure bacterial culture of an acid tolerant strain of *M. elsdenii* displaying at least a 97% similarity to a 16S ribosomal RNA sequence of the *M. elsdenii* strain CH4 deposited at NCIMB, Aberdeen, Scotland, UK under number NCIMB 41125; and
2. having a growth rate on lactate medium of at least about 0.10 h^{-1} at pH 4.5; and
3. having a growth rate on lactate medium of about 0.86 h^{-1} to about 0.94 h^{-1} at pH 5.5.

Adequate written description is provided in the present application in the form of working examples of several embodiments of the present invention of amended Claim 23.

1. **Written description of “at least a 97% similarity to a 16S ribosomal RNA sequence of the *M. elsdenii* strain CH4 deposited at NCIMB, Aberdeen, Scotland, UK under number NCIMB 41125” is provided.**

The methods of sequence analysis, the alignment of sequences, and the results obtained are described in detail in paragraphs [0105]-[0106] and [0140]-[0141] of US 2006/0257372 A1, corresponding to page 32, line 5 to page 35 line 2, and page 53, lines 4 to page 55, line 5 of PCT/ZA2003/000093. Genomic DNA was extracted from bacterial cells using standard procedures and the PCR primers used to amplify the 16S rRNA genes were selected from universally conserved regions in all eubacteria. The combination of the primers (the sequences of which are provided in Table 1 and the Sequence Listing) covered a total of 1419 nt of the 16S rRNA gene. The 16S rDNA sequences produced by PCR as described in paragraph [0105] were aligned as described in paragraph [0106]. Sequences in the profile were trimmed in order to standardize with regard to the size of the sequences of each organism included in the alignment

profile. A total of 1388 nucleotide sequence positions (97.8% of 1419 nt) were included in the profile. Percent similarity values are referenced to these 1388 unambiguously aligned nucleotide sequence positions (Paragraphs [0140]-[0141] and Tables 12 & 13). "Comparative sequencing results showed that our isolates, which are representatives of a larger phenotypically homogenous group, are between 97 and 99% similar" (paragraph [0140] of US 2006/0257372 A1, page 53, lines 4-6 of PCT/ZA2003/000093). The sequences of the isolates CH3, CH6 and CH7 in the described ribosomal sequence are thus at least 97% similar to that of the isolated strain CH4 that was deposited under the provisions of the Budapest Treaty and was given the accession number NCIMB 41125 by the International Depository Authority, NCIMB Ltd.

2. Written description of "having a growth rate on lactate medium of at least about 0.10 h⁻¹ at pH 4.5" is provided.

Working examples are provided of several of the characteristics of the isolated strains CH3, CH4, CH6, and CH7, including methods of isolation (paragraphs [0109]-[0114]), responses to modification of the growth media (paragraph [0116]), growth rates on glucose medium (paragraph [0120] and FIG. 2), and growth rates on lactate medium (paragraphs [0117]-[0119] and FIG. 1). The growth rates on lactate medium at pH 4.5 of the isolated strains CH3, CH4, CH6, and CH7 are given as 0.10 h⁻¹, 0.389 h⁻¹, 0.19 h⁻¹, and 0.15 h⁻¹, respectively (paragraph [0119] and FIG. 1).

3. Written description of "a growth rate on lactate medium of about 0.86 h⁻¹ to about 0.94 h⁻¹ at pH 5.5" is provided.

The growth rates on lactate medium at pH 5.5 of the isolated strains CH3, CH4, and CH6 are given as 0.864 h⁻¹, 0.938 h⁻¹, and 0.93 h⁻¹, respectively (paragraph [0119] and FIG. 1).

The Applicant respectfully submits that the rejection of claims 23 and 26-57 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is unwarranted in view of the present amendments and should be withdrawn.

Rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a)

Claim 24 has been rejected under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Das, U.S. Patent No. 4,138,498. The

August 1, 2008 Office Action at page 5 admits that Das does not teach strain 41125, but provides the conclusory statement “However, Das *M. elsdenii* appears the same or an obvious variant of the claimed *M. elsdenii*” (emphasis added). The Examiner makes no findings of fact and does not point to any evidence that might support this statement.

On the contrary, available evidence in the record supports the conclusion that *M. elsdenii* strains disclosed by the Das reference are not the same or an obvious variant of the claimed *M. elsdenii* strain CH4. For example, the claimed *M. elsdenii* strain CH4, when cultivated in batch as disclosed is the present specification, produced mainly acetate and propionate (paragraph [0121] of the specification as published as US 2006/0257372 A1, page 41, lines 10-11 of PCT/ZA2003/000093). However, the Das reference discloses that the strain characterized as *M. elsdenii* yields primarily butyric acid, with no acetic, propionic and lactic acids being detected (Das reference, column 2, lines 15-19, and column 4, line 40 to column 5, line 15). The claimed *M. elsdenii* strain CH4 has been characterized using phylogenetics based on 16S rRNA gene sequences, and distinguished from other strains (paragraphs [0140] – [146] of the specification as published as US 2006/0257372 A1). The Das reference does not provide any evidence to identify the strain beyond the characterization that the fermentation product is primarily butyric acid, with no acetic, propionic and lactic acids being detected. The Applicant respectfully submits that the rejection of claim 24 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Das, U.S. Patent No. 4,138,498, is unwarranted, and should be withdrawn.

CONCLUSION

In light of the amendments and arguments presented herein, the Applicant respectfully submits that all pending claims are in condition for allowance and requests a timely Notice of Allowance to follow in this case. The Applicant requests that the Examiner telephone the undersigned at (508) 860-1472 in the event that a telephone discussion would be helpful in advancing the prosecution of the present case.

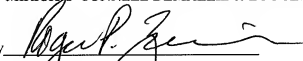
It is believed that no further fees are due with this filing. However, if any fees and/or credits are due, the undersigned authorizes any requisite fees or credits to be charged or credited to Account No. 50-1582.

September 25, 2008

Respectfully submitted,

MIRICK O'CONNELL DEMALLIE & LOUGEE, LLP

By



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Our ref: PAT 49/NCCC 16999
Your ref: A/Z(K) Patents Local LVDW/tjc
Date: 19 March 2002

Mr L S van der Walt
Adams & Adams
P O Box 1014
Pretoria 0001
Republic of South Africa

Dear Sir/Madam

**NOTIFICATION OF ACCEPTANCE OF A DEPOSIT FOR THE
PURPOSES OF PATENT PROCEDURE**

| Microorganism | Strain Number | NCIMB Number |
|----------------------|---------------|--------------|
| Megasphaera elsdenii | CH4 | NCIMB 41125 |

I have to inform you that the above designated microorganism, received on 18 March 2002 was accepted for deposit for patent purposes on 18 March 2002. You are reminded that you are bound by the terms and conditions of this acceptance set out in the Application Form signed by * on 8 March 2002 and † on 11 March 2002 a copy of which should have been retained by you.

Yours faithfully



Terence Dando, B.Sc., M.Phil.

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USSN 10/521,847
EXHIBIT A

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Registered No. SCO 78368 Registered Office: 23 St Machar Drive, Aberdeen. NCIMB Limited

P R O V I D I N G T H E S O L U T I O N

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

Kynoch Feeds (Proprietary) Ltd

P O Box 10520

Centurion 0046

Republic of South Africa

Agricultural Research
Council

P O Box 8783

Pretoria 0001

Republic of South Africa

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

Issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the
DEPOSITOR:

Megasphaera elsdenii CH4

Accession number given by the
INTERNATIONAL DEPOSITARY AUTHORITY:

NCIMB 41125

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☐

a scientific description

☒

a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on
18 March 2002 (date of the original deposit)

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depositary Authority on
(date of the original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it
on (date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: NCIMB Ltd.,

Address: 23 St Machar Drive,
Aberdeen,
AB24 3RY,
Scotland.

Signature(s) of person(s) having the power to represent the
International Depositary Authority or of authorised
official(s):

Date: 19 March 2002

Where Rule 6/4(d) applies, such date is the date on which the status of International Depositary Authority was acquired.

**BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE**

Kynoch Feeds (Proprietary) Ltd

P O Box 10520

Centurion 0046

Republic of South Africa

Agricultural Research
Council

P O Box 8783

Pretoria 0001

Republic of South Africa

INTERNATIONAL FORM

VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

TO WHOM THE VIABILITY STATEMENT
IS ISSUED

NAME AND ADDRESS OF THE PARTY

| | |
|---|---|
| I. DEPOSITOR | II. IDENTIFICATION OF THE MICROORGANISM |
| Name: AS ABOVE | Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: NCIMB 41125 |
| Address: | Date of the deposit or of the transfer ¹ : 18 March 2002 |
| III. VIABILITY STATEMENT | |
| The viability of the microorganism identified under II above was tested on 18 March 2002 ² . On that date, the said microorganism was: | |
| <input checked="" type="checkbox"/> viable | |
| <input type="checkbox"/> no longer viable | |

¹ Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

² In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.

³ Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED⁴

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: NCIMB Ltd.,

Address: 23 St Machar Drive,
Aberdeen,
A24 3RY,
Scotland.

Signature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorised official(s):

Terence Dando
Date: 19 March 2002

⁴ Fill in if the information has been requested and if the results of the test were negative.